UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ROLAND STOUGHTON, GEERT SCHMID-SCHONBEIN, TONY E. HUGLI and ERIK KISTLER

Appeal No. 2005-2235
Application No. 09/038,894

ON BRIEF

Before ADAMS, MILLS and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 10-18, 32-36, 38, 41 and 42, which are all the claims pending in the application.

Claims 10 and 32 are illustrative of the subject matter on appeal and are reproduced below:

10. A method of improving treatment outcome or reducing risk of treatment for a disease or condition, comprising:

assessing treatment options for a disease or condition by measuring cell activation levels in a subject with the disease or condition; and, if cell activation levels are elevated, administering activation lowering therapy prior to commencing treatment for the disease or condition, thereby improving treatment outcome or reducing risk of treatment.

32. A method, comprising:

assessing cell activation in a subject; and, if elevated,

administering activation lowering therapy, thereby preventing a disease or disorder or reducing the risk of a poor outcome of a treatment of a disease or disorder.

The examiner does not rely on prior art.

GROUNDS OF REJECTION

Claims 10-18, 32-36, 38, 41 and 42 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which appellants regard as the invention.

Claims 32-36, 38, 41 and 42 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to support or enable the claimed invention.

Claims 10-18, 32-36, 38, 41 and 42 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to support or enable the full scope of the claimed invention.

We reverse.

DISCUSSION

Definiteness:

Claims 10-18, 32-36, 38, 41 and 42 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which appellants regard as the invention.

According to the examiner (Answer, pages 6-7), the claims are unclear with regard to the phrases "administering activation lowering therapy" and

"preventing a disease or disorder." With regard to the phrase "administering activation lowering therapy," the examiner is unclear as to what "is being administered to create such a desired effect?" Answer, page 6. The examiner also inquires as to what is being activated. Id. Regarding the phrase "preventing a disease or disorder," the examiner is unclear as to "how the claim is to be interpreted since prevention is not taught and one of ordinary skill in the art would assume that the disease is totally absent when it is prevented." Answer, bridging paragraph, pages 6-7.

For clarity, we focus attention on the method set forth in appellants' claim 32[1]. The method of claim 32 comprises two steps:

1. assessing cell activation in a subject; and, if elevated,
2. administering activation lowering therapy,

Claim 32 requires that performance of the two-step method results in "preventing a disease or disorder or reducing the risk of a poor outcome of a treatment of a disease or disorder." See e.g. Reply Brief, page 15, "[t]he prevention or reduction in risk ... is the outcome of following the steps of the method."

The first step of appellants' method requires the assessment of cell activation in a subject. According to appellants (Brief, page 39), "it is clear to the skilled artisan what is meant by 'cell activation' as used in the claims and defined in the specification." In this regard, we note that appellants' disclose (specification, page 16),

[1] Claims 33-36, 38, 41 and 42 depend from claim 32. Claim 10, the only other independent claim from which claims 11-18 depend, requires, inter alia, the same steps as set forth in claim 32. Therefore, to focus the issues raised in this ground of rejection, we will discuss the issue with reference to claim 32.

> [a]s used herein, cell activation refers to changes in and interactions among circulating white blood cells, including leukocytes, cells lining blood vessels, including endothelial cells, and platelets. These changes are evidenced by increased "stickiness" of cells, changes in shapes of cells, free radical production and release of inflammatory mediators and enzymes.

"The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification." Miles Laboratories, Inc. v. Shandon, Inc., 997 F.2d 870, 875, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993). We read in light of appellants' specification, we understand the first step of claim 32 to refer to assessing cell activation in a subject which is evidenced by increased "stickiness" of cells, changes in shapes of cells, free radical production and release of inflammatory mediators and enzymes. As appellants' specification explains (page 17), while

> [c]ell activation is necessary for normal human immune defense mechanisms, ... inappropriate or excessive activation leads to or participates or intensifies many diseases, including, but not limited to: arthritis, atherosclerosis, acute cardiovascular incidents, Alzheimer's Disease, hypertension, diabetes, venous insufficiency, autoimmune disease and others. Cell activation is a major contributor to rejections [sic] processes in organ transplants, and to predisposition to poor outcomes in trauma and high[-]risk surgeries.

Accordingly, as set forth in claim 32, if cell activation is "elevated," then the second step of the method is performed – administering [cell[2]] activation

[2] Appellants acknowledge the typographical error in the omission of the word "cell" before the word activation. Reply Brief, pages 14 and 15. We encourage the examiner and appellants' to work together to correct this oversight.

lowering therapy. According to appellants' specification (page 19), "[a]s used herein, activation lowering therapy (A.L.T.) refers to any means in which the level of activated cells is lowered. Such means include lifestyle and dietary changes, [as well as,] drug therapy...." Therefore, we agree with the examiner finding (Answer, page 10), that the claims read "on everything from taking a day off from work to taking futhan." We note, however, that simply because appellants define the phrase "activation lowering therapy" broadly does not mean it is indefinite. "Breadth is not to be equated with indefiniteness." In re Miller, 441 F.2d 689, 693, 169 USPQ 597, 600 (CCPA 1971); see also In re Hyatt, 708 F.2d 712, 714-15, 218 USPQ 195, 197 (Fed. Cir. 1983).

Lastly, as required by claim 32, by performing the method steps, a disease or disorder is prevented, or the risk of a poor outcome of a treatment of a disease or disorder is reduced. According to the examiner (Answer, page 10), "[p]revention means to completely stop something from happening otherwise it occurs and was not prevented." We agree with the examiner's interpretation of the term, and accordingly fail to understand why the examiner finds the use of the term "preventing" as it appears in claim 32 indefinite.

Based on the foregoing analysis, we reverse the rejection of claims 10-18, 32-36, 38, 41 and 42 under 35 U.S.C. § 112, second paragraph.

Enablement:

Claims 32-36, 38, 41 and 42

Claims 32-36, 38, 41 and 42 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to support or enable the claimed invention.

According to the examiner (Answer, page 4), the phrase "thereby preventing a disease" has no support in appellants' disclosure. In this regard, the examiner finds (id.), "[t]he specification does not give any evidence to support that ... [a] disease is prevented." In response, appellants explain (Brief, page 21), "[e]xample 8 of the specification (pages 136-145) provides results of experiments employing Splanchnic Arterial Occlusion (SAO) shock models effected either by arterial clamping or by bolus injection of pancreatic homogenate." As appellants explain (Brief, page 22), SAO "in rats is a well studied model of hypotension/ischemia-reperfusion injury...." In this regard, appellants assert (Brief, page 23), in accordance with their claimed invention, "animals pretreated with serine protease [(Futhan)] prior to performance of the SAO procedure, shock and mortality is completely prevented...."

In response, the examiner asserts (Answer, page 7) that the evidence set forth in example 8 does "not prove much." According to the examiner (id.), "the rats could have died from the bout of hypotension that the [F]uthan and the pancreatic homogenate put the rat[s] through." We are not persuaded by the examiner's assertion. To the contrary, appellants' specification states (page 137), "[i]njection of whole pancreatic homogenate proved immediately fatal to

saline-treated controls while Futhan-treated rats recovered after a brief hypotension...." Focusing on the brief hypotension experienced by the Futhan-treated rats, the examiner asserts (Answer, page 8) that hypotension "is a disease or disorder which was not prevented." The examiner apparently missed the point of the experiment. As appellants point out (Brief, page 23), "[i]n animals pretreated with serine protease prior to performance of the SAO procedure, shock and mortality is completely prevented." The examiner's focus on hypotension would be relevant only if it placed the rats in shock. Appellants address this issue head on, asserting that "[t]he transient decrease in blood pressure or brief hypotension that was reported in animals pretreated with serine protease ... is not tantamount to shock." Brief, page 23. The examiner does not dispute this assertion. Accordingly, we find that the weight of the evidence falls in favor of appellants.

There is no doubt that the scope of appellants' claimed invention is very broad. Appellants, however, have provided an enabling description (example 8) of the "prevention" of a disease – shock. The examiner does not dispute that the methodology set forth in example 8 is within the scope of appellants' claimed methods. In all, beyond conjecture, the examiner offers no evidence to support a finding of non-enablement. In this regard, we remind the examiner, "[w]hen rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the

application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement." In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). It is, however, "incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

On this record, despite the evidence set forth in appellants' specification, the examiner maintains the enablement rejection based on nothing more than an opinion. The examiner makes no attempt to favor this record with an evidentiary basis to support his opinion. Accordingly, we find the weight of the evidence favors appellants. The rejection of claims 32-36, 38, 41 and 42 under 35 U.S.C. 112, first paragraph is reversed.

Claims 10-18, 32-36, 38, 41 and 42

Claims 10-18, 32-36, 38, 41 and 42 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to support or enable the full scope of the claimed invention.

According to the examiner (Answer, page 5), while appellants' specification provides an enabling disclosure "for treating hemorrhagic shock by assessing for free radical production using phenol red and then if levels are

elevated, using [F]uthan," appellants' specification does not provide an enabling disclosure "for any and all activation lowering therapies[,] and any and all diseases or conditions[,] and any and all methods of assessing cellular activation[.]" In this regard, the examiner asserts (id.), "[t]he art of biotechnology is a highly unpredictable art[3] and it would be an undue burden for one of ordinary skill in the art to test any and all activation lowering therapies and any and all diseases or conditions and any and all methods of assessing cellular activation to see if they could perform the claimed processes." In the examiner's opinion (Answer, pages 5-6),

> knowing only one activation lowering therapy, one condition to treat it with and only one type of assay in which to determine if it is necessary, one of ordinary skill in the art would not know what other conditions could be treated, what other therapies could be used or what other assays could be used to determine if such a method would work. ... There is no guidance on which assay would be useful for which disease/condition.

In response, appellants point out that the therapeutic target and diagnostic indicator is cell activation. Brief, page 24. In this regard, appellants' note (id.), "[n]umerous methods and ways to lower cell activation[4] are provided in the specification (see, discussion above regarding the claimed subject matter); these methods range from particular drugs, such as [F]uthan, to lifestyle changes." According to appellants (id.),

> [p]rior to the instant application ... cell activation had not been identified as a diagnostic or prognostic of disease or treatment outcome nor as a point of therapeutic intervention. Having

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[3] According to the examiner (Answer, page 5), "[t]he area of biotechnology is highly unpredictable since the human body in and of itself is very unpredictable."

[4] Appellants explain (Brief, page 24), "[c]ell activation is a phenomenon that is known to those of skill in the art as are factors that lead to its elevation and some methods for its decrease."

> identified it as such in the instant application, then the particulars for practicing each step in the method, from testing the levels of cell activation to methods for lowering levels, are known to those of skill in the art.

In response, the examiner makes no attempt to favor this record with evidence to rebut appellants' arguments. Instead, the examiner simply reasserts that the phrase "administering activation lowering therapy" is broad, and the phrase "preventing a disease or disorder" is indefinite. Answer, page 10. Both of these issues were discussed above. Further, we note that simply asserting that a claim term or phrase is broad, is not a sufficient basis to maintain a rejection under the enablement provision of 35 U.S.C. § 112, first paragraph.

Accordingly, we find the weight of the evidence favors appellants. The rejection of claims 10-18, 32-36, 38, 41 and 42 under 35 U.S.C. § 112, first paragraph is reversed.

OTHER ISSUES

In the event of further prosecution, we encourage the examiner to take a step back and reconsider the scope of the claimed invention together with any available prior art. There can be no doubt that appellants' claimed invention is broad. See e.g., the foregoing discussion and the examiner's assertions regarding the rejections under 35 U.S.C. § 112, first and second paragraphs. Focusing again on claim 32, as we understand it, claim 32 reads on any method whereby cell activation is assessed, and action (including bed rest) is taken. In this regard, we find no requirement in appellants' claims or specification, that a blood test or other "procedure" be used to assess cell activation. Accordingly, the claim reads on a subject recognizing that the subject is experiencing

inflammation. It would seem quite clear to us that inflammation results from the release of inflammatory mediators. Therefore, administering an anti-inflammatory to the subject would prevent a disease or disorder that is within the scope of appellants' claimed invention. In this regard, we not that page 10 of appellants' specification discloses

> [a]s used herein, treatment means any manner in which the symptoms of a conditions [sic], disorder or disease are ameliorated or otherwise beneficially altered. Treatment also encompasses any pharmaceutical use of the compositions herein.
>
> As used herein, amelioration of the symptoms of a particular disorder by administration of a particular pharmaceutical composition refers to any lessening, whether permanent or temporary, lasting or transient that can be attributed to or associated with administration of the composition.

In this regard, we direct the examiner's attention to Adams et al. (Adams), United States Patent No. 5,447,957, which issued September 5, 1995. According to Adams (column 1, lines 10-14), "[a]n early event in the response of most inflammatory cells to immunologic activation and other stimuli is the release of newly formed products (mediators) which alter the function and biochemistry of surrounding cells and tissues." Therefore, most subjects experiencing inflammation will have elevated levels of inflammatory mediators. Adams proposes to treat this condition by administering a compound of Formula (I). See abstract, and column 4, line 50 – column 5, line 17.

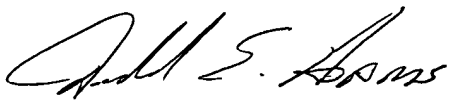
Accordingly, prior to any further action, we encourage the examiner to reconsider the scope of appellants' claims, together with Adams, and any other relevant prior art to determine whether appellants' claims are free of the prior art.

SUMMARY

All rejections of record are reversed.

Other issues are raised for the examiner's consideration.

REVERSED



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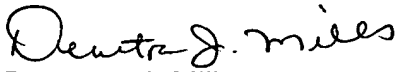
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Lora M. Green)
Administrative Patent Judge)

DEA/lbg

FISH & RICHARDSON, PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022